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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
FLORY, CHRISTOPHER A	
ART UNIT	PAPER NUMBER
3762	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/630,547	MARSHALL ET AL.	
	Examiner	Art Unit	
	CHRISTOPHER A. FLORY	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 March 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,7-19 and 49-58* is/are pending in the application.

4a) Of the above claim(s) *49-58* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 7-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/23/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 29 March 2009 has been entered.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 23 March 2009 was filed after the mailing date of the Final Office Action on 21 October 2008. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Election/Restrictions

3. Newly submitted claims 49-58 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

The new claims (Group II) and the original claims (Group I) are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice

another and materially different process. (MPEP § 806.05(e)). In this case the device leads of group I can be implanted in tissue other than heart tissue or may be places exterior to the heart. The process of group II can be practiced by a device set up for monopolar or multi-polar stimulation rather than bipolar stimulation as required in group I. The device of group I can stimulate at both sites, whereas group II requires that the second site is not stimulated.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 49-58 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Terminal Disclaimer

3. Applicant proposes in their Response that the terminal disclaimer filed on 20 June 2008 be withdrawn since the claims have been substantially modified. However, it is noted that even though claim 1 has been amended, it is not seen that its scope has been substantially changed. It was already previously understood that there was a first lead and second lead through disclosure of a first lead body and second lead body. It was already understood that there was a first and second conductor and first and second connector. A pacemaker is synonymous with a pacing pulse generator. The first and second polarities were understood through the cancelled limitation of bipolar stimulation. The only marked change to the claim is that the porous layer no longer has

to comprise silicone or collagen, thus broadening the claim and making a terminal disclaimer that much more necessary.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1, 2 and 7-19 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10, 14-18, 22, and 25-27 of U.S. Patent No. 7,191,016. Although the conflicting claims are not identical, they are not patentably distinct from each other because the component of a second elongated lead body in independent claims 1 and 20, and dependent claim 44 of the instant application does not distinguish over the device embodied in the independent claim of the '016 patent because it shares a common functionality, and a device with a first and second lead bodies is a reasonable embodiment thereof. It is well known in the field that medical lead electrodes can be placed either adjacent to each other on one lead body when intended for placement within the same chamber (e.g. the right ventricle) or placed each on its own lead body for the sake of placement across different barriers of the heart (e.g. one in the right ventricle and the other in a cardiac vein), both embodiments being for the purpose of pacing/sensing in a localized region of the heart.

Response to Arguments

6. Applicant's arguments with respect to claims 1, 2 and 7-19 have been considered but are moot in view of the new ground(s) of rejection.

It is noted that each of the references is considered to read on the claims since independent claim 1 merely recites a first lead body with a first conductor and a

proximally located connector, and a second lead body with a second conductor and a proximally located second connector. Even a y-shaped connection reads on this limitation which merely requires that there be two separate proximal connectors connected to separate elongated bodies, which can clearly be seen in each of the references even in they y-shaped configuration. Additionally, the Belden reference even clearly shows a two-lead configuration in Fig. 2.

Each of the references also reads on the further limitation that the first electrode is connected to the first conductor and the second electrode is connected to the second separate conductor as seen in the figures and referenced herein below. The claim language merely recites that the two electrodes be located at a first and second site and that they be connected to their respective connectors via their respective conductors, and doe not limit further the configuration of the enclosure at the electrode locations.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Line two of claim one appears to have been amended to read “the implantable including a cardiac pacing pulse generator.” This language is confusing as it is unclear what implantable is referring to.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 1, 2, 7-10, and 16-18 stand rejected under 35 U.S.C. 102(b) as anticipated by Carson (US Patent Number 5,931,862, hereinafter Carson'862).

Regarding claims 1 and 2, Carson'862 shows a medical electrical lead (Figs. 1 and 2, lead 12) comprising a first elongated body with a first elongated insulated conductor (elongated body 10', conductor 36) and a first connector at its proximal end (connector 22); a second elongated lead body with a second conductor (column 4, lines 52-63; Figs. 1 and 2, lead 10" and conductor 37) and a second connector at its proximal end (connector 24); a first low voltage electrode adapted for intimate contact with tissue to provide pacing stimulation (Figs. 2 & 3, distal pacing electrode 20, helical coil or tined formations); a second low voltage electrode joined to the lead body in proximity to the first electrode (underlying electrode 16); and a porous layer formed over the second electrode (porous tubular covering 10); wherein the outer surface of the second electrode (16) is recessed from the outer surface of the lead body (Fig. 2) and the outer

surface of the porous layer (10) is isodiametric with the outer surface of the lead body (column 2, lines 39-44).

Further regarding claim 1, Carson'862 discloses that the layer 10 covering the electrodes may be impregnated with collagen via perfusion, which is taken to reasonably disclose a sheet of collagen fibers, since the ePTFE sheet will be evenly distributed with the perfused collagen fibers (column 8, lines 50-65).

Carson '682 discloses that the porous layer is adapted to prevent chronic tissue ingrowth (column 2, lines 47-48). The prevention of chronic tissue ingrowth, which prevents the electrode from coming in direct contact with the tissue, is a sufficient and effective means of preventing the electrode from stimulating tissue in proximity to the electrode. Alternatively, the pulse generator (Fig. 1, generator 11) of Carson'862 must inherently contain a control means used in the art, such as a microprocessor. That control means provides a means for preventing the second electrode from stimulating the tissue as the alternate state to control-driven stimulation of tissue. If the device is off, or the second electrode channel is powered down or in a blanked state, the control means is preventing the second electrode from delivering stimulation to the tissue.

Regarding claims 7-10, Carson’862 discloses a means to promote wetting comprising a wetting agent which can be a surfactant and a surface treatment of the porous layer (column 2, line 54 through column 3, line 26).

Regarding claim 16, Carson‘682 discloses the invention as previously recited wherein the porous layer is adapted to prevent chronic tissue ingrowth (column 2, lines 47-48).

It is alternatively noted that the component of a second elongated lead body in the instant application does not distinguish over the device of Carson'682 because it shares a common functionality, and a device with a first and second lead bodies is a reasonable embodiment of the Carson'682 system, where connector branches 22 and 24 with porous coverings 10' and 10'' could extend for the full length of the device and in such a configuration constitute a first and second lead body, each containing one of the pacing/sensing electrodes and capable of being implanted in the cardiac vein or the right ventricle (as shown in Figure 1).

11. Claims 1, 2, 7-10, 11 and 16 are rejected under 35 U.S.C. 102(e) as being anticipated by Krall et al. (WO 02/089909 A1).

Regarding claims 1 and 2, Krall et al. shows a medical electrical lead (Fig. 1, lead body 6) comprising a first elongated body with a first elongated insulated conductor and a first connector at the proximal end (connector 4, lead body leading to y-junction); a second elongated lead body comprising second elongated insulated conductor and second connector at the proximal end (the other connector 4 and lead segment; alternatively Fig. 2 coiled electrical conductor 14, second electrical conductor 16); a first low voltage electrode adapted for intimate contact with tissue to provide pacing stimulation (Fig. 2, distal tip electrode 10); a second low voltage electrode joined to the lead body in proximity to the first electrode (coiled electrode portion 8, coiled electrode 24); and a porous layer formed over the second electrode (porous thin film 30); wherein the outer surface of the second electrode (24) is recessed from the outer surface of the

lead body (Fig. 2) and the outer surface of the porous layer (30) is isodiametric with the outer surface of the lead body (column 2, lines 39-44).

Regarding claims 7-10,11 and 16, Krall et al. discloses that the cover comprises a porous polymer (claim 1), preferably ePTFE (claim 8); is relatively thin, on the order of .13mm (or .005inches) thick (page 3, lines 5-6; page 10, lines 26 through page 11, line 4); is adapted to prevent chronic tissue ingrowth (page 3, lines 10-13); and comprises a means of wetting (claims 13-14, surfactant polyvinyl alcohol).

It is alternatively noted that the component of a second elongated lead body in the instant application does not distinguish over the device of Krall et al. because it shares a common functionality, and a device with a first and second lead bodies is a reasonable embodiment of the Krall et al. system, where connectors (4) could extend for the full length of lead assembly (2) and in such a configuration constitute a first and second lead body, each containing one of the pacing/sensing electrodes and capable of being implanted in the cardiac vein or the right ventricle (as shown in Figure 1).

12. Claims 1, 2 and 16-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Belden (US Patent 6,847,845, hereinafter Belden'845).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Regarding claims 1, 2, and 16-19, Belden'845 discloses a medical system comprising an implantable medical device (80; Fig. 5); a first lead comprising a first elongated lead body with a first connector at the proximal end (lead 200, connector 206) implanted in a cardiac vein with a first electrode (12) adapted for intimate contact with tissue and a second lead comprising an elongate lad body with a connector at the proximal end (lead 201, connector 214) and a second electrode (16) with a porous layer (32) formed over the second electrode which may be isodiametric and comprised of ePTFE, silicone, or polyurethane (column 3, lines 20-25, 47-56) and adapted to prevent chronic tissue ingrowth (column 3, line 64 through column 4, line 5); and comprising a third high voltage electrode adapted for defibrillation stimulation (defibrillation coil 74).

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. Claims 11-14 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Carson'862 in view of Hull et al. (US Patent 5,269,810, hereinafter Hull'810).

Carson'862 shows the invention substantially as claimed, but does not disclose the thickness of the porous layer (2-9 mm) or the desired size range for the pores in that layer (0.4-50 microns).

In the same problem solving area, Hull'810 teaches an electrode-covering layer that is about 0.13 mm (0.005 inches) thick with fibril length (i.e. internodal distance and pore size) of 10 microns for the advantages of being highly biocompatible, highly flexible, and long-lasting (column 3, lines 32-45; column 4, lines 1-15).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to use similar structural criteria with the Carson'862 invention for the same advantages of biocompatibility, flexibility and long lifespan (motivation to combine provided by Hull et al., column 3, lines 32-45; column 4, lines 1-15).

15. Claims 12-15 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Carson'862 in view of Soukup et al. (US Patent 5,466,252).

Carson'862 shows the invention substantially as claimed, but does not disclose the desired size range for the pores in that layer (0.4-50 microns).

In the same field of endeavor, Soukup et al. teaches an implantable lead with a porous PTFE layer with preferred fibril lengths greater than 4 microns, and most preferably greater than 10 microns to provide the necessary amount of flexibility and extensibility for the intended application and to present an acceptable biocompatible surface to the blood chemistry to which the outer surface of the lead will be exposed (column 2, lines 26-34).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to use similar parameters for the lead body covering in the Carson'862 invention to provide the same advantages of flexibility and biocompatibility (motivation to combine provided by Soukup et al., column 2, lines 26-34).

16. Claim 19 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Carson'862 in view of Kroll (US Patent 6,327,498).

Carson'862 shows the invention substantially as claimed, but does not disclose a third high voltage electrode adapted for defibrillation stimulation.

In the same field of endeavor, Kroll'498 teaches a third electrode (Fig. 2, electrode 46) placed proximal to a second electrode (32) and distal to a first electrode (34) for the purpose of providing shocking stimulation pulses (column 7, lines 64-67).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to include a third electrode in the Carson'862 device for the same advantage of applying shocking stimulation (defibrillation) to the heart (motivation to combine provided by Kroll'498 column 7, lines 64-67).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher A. Flory whose telephone number is (571) 272-6820. The examiner can normally be reached on M - F 8:30 a.m. to 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Christopher A. Flory/

13 April 2009

/George Manuel/
Primary Examiner